UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/804,592	03/19/2004	William Galbraith	80154	9558

26253 7590 04/25/2006

DAVID W. HIGHET, VP AND CHIEF IP COUNSEL
BECTON, DICKINSON AND COMPANY
1 BECTON DRIVE, MC 110
FRANKLIN LAKES, NJ 07417-1880

EXAMINER	
YU, MELANIE J	

ART UNIT	PAPER NUMBER
1641	

DATE MAILED: 04/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/804,592	GALBRAITH, WILLIAM	
	Examiner	Art Unit	
	Melanie Yu	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6,24-31,50 and 51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6,24-31,50 and 51* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *19 March 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 6 February 2006 has been entered.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1-6 and 24-27 are rejected under 35 U.S.C. 102(b) as being anticipated by Sundrehagen (US 5,919,708).

Sundrehagen teaches an apparatus comprising an insoluble support (a solid support of beads of cross-linked agarose are insoluble; col. 11, lines 46-49) having a ligand comprising bromosulfophthalein attached thereto (bromosulphophthalein-glutathione ligand comprises bromosulphophthalein, which is the same as bromosulfophthalein, col. 11, lines 46-51), wherein the insoluble support is contained or supported in a container of columns (separation is obtained by filtering through a filter comprising a filter surface, wherein the filter surface is an insoluble support and the filter is a container, col. 11, lines 19-25). Sundrehagen further teaches the filter container being a filter plate (col. 11, lines 21-25) and the insoluble support being a matrix (col. 11, lines 47-48).

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. Claims 24 and 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pieper et al. (US 2002/0127739) in view of Sundrehagen (US 5,919,708).

Pieper et al. teach a column comprising one or more additional supports capable of binding one or more non-albumin proteins (par. 0067), wherein the supports include one or more supports capable of binding IgA and IgG (different matrices carrying different binding agents to remove proteins from a sample is provided at par. 0067; sample proteins of IgG and IgA are non-albumin and are listed at pg. 9, Table 1). Pieper et al. fail to teach a ligand of bromosulfophthalein.

Sundrehagen teaches a ligand comprising bromosulfophthalein attached to an insoluble support (col. 11, lines 46-65) of a filter plate (col. 11, lines 21-25), in order to detect albumin bound to a support.

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the column of Pieper et al., a binding agent of bromosulfophthalein as taught by Sundrehagen, in order to provide a detectable ligand specific to albumin, which strongly influences the affinity of albumin to the ligand and provides detectable properties upon binding which ensures removal.

Regarding claims 30 and 31, Pieper et al. teach a support bindable to IgA (proteins for which a multi-component antibody affinity matrix are listed at pg. 9, Table 1; IgA has a separate column body par. 0102) and a support bindable to IgG (proteins for which a multi-component antibody affinity matrix are listed at pg. 9, Table 1; IgG has a

separate column body par. 0102) wherein the support comprises protein A and G cartridge (a column comprising protein G and A bind IgG; see under Table 1).

3. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sundrehagen (US 5,919,708), as applied to claim 1, in view of et al. (US 6,680,176) further in view of Shi et al. (US 5,919,626).

Sundrehagen teaches a ligand comprising bromosulfophthalein attached to an insoluble support, but fails to teach the ligand attached via an epoxy linkage.

Ebersole et al. teach a hydroxyl group of a molecule covalently bound to a substrate through an epoxy linkage (matrix is epoxy activated and therefore molecules bind with the matrix through the activated epoxy, which would be an epoxy linkage, col. 15, line 53-col. 16, line 16), in order to provide a covalent bond between the ligand and the substrate.

Shi et al. teach that an epoxy linkage to a receptor agent is beneficial because the linkages are stable to heat, high salt and elevated temperatures (col. 9, lines 1-14).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the apparatus of Sundrehagen, to the hydroxy group on the ligand to the substrate via an epoxy linkage as taught by Ebersole et al., in order to provide linkages that are stable in heat and elevated temperatures as taught by Shi et al. The ligand of bromosulphophthalein-glutathione as taught by Sundrehagen teaches a hydroxy group.

4. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pieper et al. (US 2002/0127739) in view of Sundrehagen (US 5,919,708), as applied to claim 24, in view of Matzinger et al. (US 6,680,176) further in view of Shi et al. (US 5,919,626).

Sundrehagen teaches a ligand comprising bromosulfophthalein attached to an insoluble support, but fails to teach the ligand attached via an epoxy linkage.

Ebersole et al. teach a hydroxyl group of a molecule covalently bound to a substrate through an epoxy linkage (matrix is epoxy activated and therefore molecules bind with the matrix through the activated epoxy, which would be an epoxy linkage, col. 15, line 53-col. 16, line 16), in order to provide a covalent bond between the ligand and the substrate.

Shi et al. teach that an epoxy linkage to a receptor agent is beneficial because the linkages are stable to heat, high salt and elevated temperatures (col. 9, lines 1-14).

Therefore it would have been obvious to one having ordinary skill in the art at the time the invention was made to include in the apparatus of Sundrehagen, to the hydroxy group on the ligand to the substrate via an epoxy linkage as taught by Ebersole et al., in order to provide linkages that are stable in heat and elevated temperatures as taught by Shi et al. The ligand of bromosulphophthalein-glutathione as taught by Sundrehagen teaches a hydroxy group.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 1-6 and 24-31 provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-6 and 24-31 of copending Application No. 10/922,560. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

Response to Arguments

5. Applicant's arguments filed 6 February 2006 have been fully considered but they are not persuasive. Regarding the rejection of claims 1-6 and 24-27 under 35 USC 102(b) over Sundrehagen, applicant argues that bromosulphophthalein-glutathione is an immobilized ligand, but does not comprise bromosulfophthalein. Applicant also argues that Sundrehagen teaches a second signal forming agent of bromosulfophthalein, which is different from bromosulphophthalein and is not attached to a substrate. In response to applicant's arguments, regarding that bromosulphophthalein-glutathione does not comprise bromosulfophthalein, at paragraph 3 of the previous office action dated 1 November 2005 states that the immobilized ligand taught by Sundrehagen at column 11 is not bromosulphophthalein. However, the ligand immobilized to the substrate *comprises* bromosulphophthalein. Because claim 1 uses the open claim language "comprising" the ligand must only include bromosulfophthalein and does not exclude other compounds from the ligand. Therefore a compound of bromosulphophthalein-glutathione comprises bromosulphophthalein. Applicant appears to argue that bromosulphophthalein and bromosulfophthalein are different compounds. However, the compound, bromosulfophthalein, of rejected claim 1 is the same compound as that taught by Sundrehagen at column 11, lines 46-51 as evidenced by the instant specification and Kolobe et al. (Characterization of bromosulphophthalein binding to human glutathione S-

transferase A1-1: thermodynamics and inhibition kinetics, 2004, Biochem. J., pgs. 703-709). The compound of bromosulphophthalein is shown on page 2 Fig. 1C of Kolobe et al., which is identical to the compound submitted as bromosulfophthalein on 6 February 2006 as an amendment to replace the structure on page 5 of the original specification. Therefore Sundrehagen teaches a ligand of bromosulphophthalein-glutathione, which comprises bromosulfophthalein, attached to a substrate.

Applicant also argues that the second signal forming dye of bromosulfophthalein taught at column 8, line 6 of Sundrehagen, is not immobilized or attached to a substrate. It is noted that this portion of the Sundrehagen reference is not relied upon for the current rejection. However, in response to applicant's arguments, rejected claim 1 does not require bromosulfophthalein to be immobilized directly to the substrate. Sundrehagen teaches that the second signal forming dye may bind to albumin which is attached to the substrate through an albumin binding ligand. Therefore, the second signal forming dye would be attached to the substrate through the albumin and albumin binding ligand to indicate the binding of albumin, which is the limitation required by the rejected claims.

With respect to applicant's amendment regarding the double patenting rejection of claims 1-6 and 24-31, claims 1-6 and 24-31 have not been cancelled from co-pending application 10/922,560. Until these claims have been cancelled, the provisional double patenting rejection is proper.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie Yu whose telephone number is (571) 272-2933. The examiner can normally be reached on M-F 8:30-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Melanie Yu
Patent Examiner
Art Unit 1641

LONG V. LE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600
04/10/06